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09/397,342	09/15/99	ADAMS	P1626R1

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HM12/0504

EXAMINER

TUNG, M

ART UNIT

PAPER NUMBER

1644

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/397,342

Applicant(s)

Adams, et al

Examiner

Mary B. Tung

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Feb 26, 2001

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-16 and 44-46 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-16 and 44-46 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 and 6

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

### ***DETAILED ACTION***

#### ***Election/Restriction***

1. Applicant's election of Group I, claims 1-16 and newly-filed claims 44-46 in the paper filed February 26, 2001, Paper No. 9 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Groups II-VII, claims 17-43 have been cancelled by Applicants without prejudice.

#### ***Specification***

3. The use of the trademarks such as "SEPHADDEX", and "SEPHAROSE", page 31, line 7, "GENBANK", page 48, line 4, "MACVECTOR", page 48, line 12, "TAQMAN", page 65, line 2, and so forth of the specification has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
4. Each letter of the trademarks must be capitalized. *See MPEP 608.01(V) and Appendix 1.*
5. The instant application discloses a hyperlink on page 9, line 12. The disclosure of a hyperlink is objected to because it contains an embedded and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other browser-executable code.
6. When a patent application with embedded hyperlinks and/or other forms of browser-executable code issue as a patent and the patent document is placed on the PTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. PTO policy does not permit the PTO to link to any commercial sites since the PTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. See MPEP § 608.01.
7. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an

improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding incorporation by reference.

***Claim Rejections - 35 U.S.C. § 101 and Claim Rejections - 35 U.S.C. § 112***

8. 35 U.S.C. § 101 reads as follows:  
"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-16 and 44-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility.

11. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001. In keeping with the utility guidelines and corresponding training materials (available on the PTO Website), none of the disclosed uses is a specific and/or substantial use.

12. While Applicant asserts specific utilities for the claimed invention (use of the protein to predict the onset of obesity (see page 38), or to treat fever (see page 39)), these are not considered to be substantial utilities for the following reasons. These utilities are premised on the limited similarity of the disclosed full length protein (SEQ ID NO: 2 as encoded by SEQ ID NO: 1) to UCP. The specification discloses 29% identity with UCP1, 33% identity with UCP2 and 34% identity with UCP3 over a 323 amino acid sequence (see page 16). No single effect of UCP is ascribed to the claimed protein. Note that while the specification produces the full-length protein recombinantly, no biological activity is established for the full-length protein or any of the claimed fragments thereof. As such, further research would be required to identify or reasonably confirm a "real world" context of use. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved would be required. Therefore, the specification does not fairly disclose a substantial utility for the claimed embodiments.

13. Asserted utilities such as for gene probes and chromosomal markers are not specific (see page 31) as set forth in the guidelines.

14. Claim 1-16 and 44-46 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 U.S.C. § 112***

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Applicant is directed to the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday, January 5, 2001. In keeping with the written description guidelines and corresponding training materials (available on the PTO Website), the claimed invention lacks adequate written description in the specification.

17. Claims 7, 9 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

18. The claims recite an amino acid sequence having at least 80%, 90% or 95% sequence identity to the sequence of SEQ ID NO: 1. The specification provides no guidance as to the activity encompassed by the claimed polypeptides encoded by the nucleic acids having at least 80%, 90% or 95% sequence identity to the sequence of SEQ ID NO: 1. The essential element of the invention is the characteristics of the UCP polypeptide, however, the Applicants have not provided disclosure in the specification as to the structure and function relationship that is essential to the claimed nucleic acid sequence and its encoded polypeptide. The specification and claims do not indicate what distinguishing attributes are shared by the members of the claimed genus. The scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and the claims do not provide any guidance as to what changes should be made or what structural features that could distinguish compounds in the genus from others in the genus are missing from the disclosure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variable, SEQ ID NO: 1 alone is insufficient to describe the genus or the claimed methods. Additionally, Attwood (*Science*

290(5491):471-473, Oct. 27, 2000) teaches that "It is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences (and it is not always clear what we mean by "function"); very few structures are known compared with the number of sequences, and structure prediction methods are unreliable (and knowing structure does not inherently tell us functions)" [parentheses added by author]. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *see University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

19. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.
20. Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.
21. The phrase "DNA encoding a polypeptide scoring at least 80% positives..." is unclear. It is unclear whether Applicants intend to recite a polypeptide with homology of 80% to the claimed polypeptide, or how the "positives" would be "scored". It is suggested that the Applicants use a more standard claim language construction to clarify the claim.

#### ***Claim Rejections - 35 U.S.C. § 102***

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:  
A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
23. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Hillier, et al. (GenBank Accession No. AW157357).
24. Hillier, et al. teach a 483 nucleotide sequence with 100% homology over residues 40-399 of SEQ ID NO: 2 and encodes a 161 amino acid polypeptide sequence which is identified as an uncoupling protein 4. The taught sequence of Hillier would hybridize under the conditions recited in claim 4, absent evidence to the contrary. Therefore, the reference teachings anticipate the claimed invention.

*Conclusion*

25. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

May 3, 2001  
Mary B. Tung, Ph.D.  
Patent Examiner  
Group 1640

*Mary B Tung*  
**MARY BETH TUNG, PH.D.**  
**PATENT EXAMINER**